K003185

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MAR 2 0 2001

510(k) Summary
Full Spectrum Activator® III

Manufacturer:

Activator Methods, Inc.
3714 E. Indian School Road
Phoenix, Arizona 85060-0317

Contact:

Arlan W. Fuhr, D.C.
Phone: (602) 224-0220
Fax: (602) 224-0230

Trade name:

Full Spectrum Activator® III

Common name:

chiropractic adjusting device

Classification name:

Plunger-like joint manipulator

Substantial equivalence:

Activator® I *preamendments device*
Activator Methods, Phoenix, Arizona

Activator® II K973506
Activator Methods, Phoenix, Arizona

Intended Use:

The Full Spectrum Activator® III is intended for chiropractic adjustment of the spine and extremities.

Device Description:

The Full Spectrum Activator® III is a chiropractic adjusting instrument for use in spinal manipulative therapy. The instrument is approximately 8 inches in length and approximately 2.5 inches wide at the handles. The major components of the device include two handles for holding the device (first handle) and applying thrust force (second handle), a thrust element for delivering an input force to the patient, a body contact member, a spring for propelling the stainless steel thrust element into a stainless steel stylus, a conical aluminum shell, a stainless steel nose piece, and a precision force adjustment mechanism. The body contact member is manufactured from silicone rubber.

The precision adjustment mechanism is used to manually adjust the magnitude of the kinetic energy imposed by the hammer on the stylus. The nosepiece is affixed to the end of the conical aluminum shell. The stylus moves freely within the nosepiece, which is attached to the end of a conical aluminum shell. The hammer is completely enclosed by the conical aluminum shell and nosepiece. The Full Spectrum Activator® III has three discrete dynamic force settings labeled 1 (lowest force setting) to 3 (highest force setting).

Comparison to predicate device:

Table 1. Substantial Equivalence Comparison

	Activator® I	**Activator® II**	**Activator® III**
Indicated for chiropractic adjustment of the spine?	Yes	Yes	Yes
Hand held adjusting device?	Yes	Yes	Yes
Impact force delivered by spring energy?	Yes	Yes	Yes
Adjustable impact force?	Yes	Yes	Yes
Silicone rubber body contact member?	Yes	Yes	Yes
Weighted anvil tip?	No	Yes	Yes
Pre-load isolation frame?	No	No	Yes
Precision pre-load force setting?	No	No	Yes
Precision operating force setting?	No	No	Yes

Summary of data upon which substantial equivalence was based:

Bench data for the Full Spectrum Activator® III indicated that the addition of the pre-load control frame improved the force-frequencies characteristics of the device significantly. A comprehensive series of force analysis tests were performed on the Activator® I, Activator® II, and the Full Spectrum Activator® III. The Activator family of devices produce dynamic force-time histories that are low in amplitude (<200 N) and very short in duration (<5 milliseconds), and are therefore classified as "impulsive forces". There is a substantial improvement in the dynamic force area ratio for the Full Spectrum Activator® III in comparison to the Activator® I and Activator® II devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2001

Dr. Arlan W. Fuhr
President and Co-Founder
Activator Methods International
3714 East Indian School Road
Phoenix, Arizona 85018

Re: K003185
Trade Name: Full Spectrum Activator® III
Regulatory Class: II
Product Code: 89 LXM
Dated: January 25, 2001
Received: February 5, 2001

Dear Dr Fuhr:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Full Spectrum Activator® III Indications for Use Enclosure

510(k) Number: K003185

Device Name: Full Spectrum Activator® III

Indications for Use: The Full Spectrum Activator® III is indicated for chiropractic adjustment of the spine and extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CRDH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use _____

(Per 21 CFR 801.109)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003185

02/02/01